OFFICE OF ACQUISITIONS
NATIONAL CANCER INSTITUTE

REQUEST FOR PROPOSAL NUMBER: N02CM27024-82

Amendment No.: 1

Date of Issuance: March 23, 2012

The above numbered Request For Proposal (RFP) is amended as set forth below. The hour and date specified for receipt of Offerors remains unchanged.

Offerors MUST acknowledge receipt of the amendment prior to the hour and the date specified in the solicitation or as amended, by separate letter, telegram, or Electronic Mail which includes a reference to the RFP and Amendment number(s). For your convenience, the Proposal Intent Response Form is provided in SECTION J - List of Attachments of this RFP, for this purpose.

FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERORS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER.

This Amendment addresses questions received in response to the RFP as stated below:

I. Below are the Technical Questions received and the Government's responses:

1. Can it be assumed that each bulk drug substance will in fact require a method development/validation exercise to be completed or are some of the methods already established, but just need transferred to another lab?

As described in the Statement of Work (Attachment #3), approximately 2-3 new drug substances/year will need method development and validation. The analysis of bulk drug lots (4-6 lots/year), however, will follow established methods.

2. Will the NCI or its sources be able to provide reference standards to the bulk drug substances?

NCI will supply reference standards for all assigned drug substances.

3. The Technical Proposal Instructions (Attachment #4, Page 6, Organization Support and Experience, Section e.) states: "Please submit three (3) copies of the organization's safety manual." To support sustainable practices if the organization's Safety Manual is over 300 pages, would an electronic submittal (.pdf) of the Safety Manual only via three (3) separate CDs or DVDs support the Section e requirement?

Either hard copy or electronic format of the Safety Manual will be sufficient.

II. Below are the Cost Questions received and the Government's responses:

1. The project says that it is a re-competition of the following contracts: "This project represents a recompetition of the following contracts: Midwest Research Institute (HHSN261200722001C), Research Triangle Institute (HHSN261200722002C), and SRI International (HHSN261200722003C)." Can you tell me if these previous contract holders are looking to outsource some of the existing projects, are no longer in business, or whether there is any other reason you can share that these projects are looking to be re-negotiated with other companies?

The contracts are being recompeted because they have reached the end of the five year period indicated in the initial contract award. We are unable to provide any additional information regarding the status of the current contractors.

2. As you know, method validation involves multiple elements that often take a considerable amount of time to complete. Will this contract be awarded such that the awardee(s) can bill at milestone completions for the validation work?

This contract is anticipated to be awarded as a Cost Reimbursement contract. The Contractor will prepare a monthly invoice to NCI for actual costs incurred in the previous month.

3. In accordance with FAR 15.403-1, the Contracting Officer shall not require certified cost or pricing data if it is determined that prices agreed upon are based upon adequate price competition. Since there are three incumbents and the RFP states that multiple awards (anticipated three) will be made, it can be assumed that multiple bids will be received and that prices will be estimated based on the fact that there will be competition. Would the NCI consider removing the requirement for Certified Cost and Pricing Data in this instance?

While we currently have three contracts in support of this project, we cannot assume that we will receive multiple proposals as a result of this RFP. Based on this uncertainty, the requirement for Certified Cost and Pricing Data will remain.

Nothing follows.